(19) Europäisches Patentamt
European Patent Offic
Office européen des brevets

(11) Publication number : **0 481 685 A1**

(12) EUROPEAN PATENT APPLICATION

(21) Application number : **91309336.5**

(51) Int. Cl.[5] : **A61B 19/00,** A61B 17/34

(22) Date of filing : **10.10.91**

(30) Priority : **15.10.90 US 597575**

(43) Date of publication of application :
22.04.92 Bulletin 92/17

(84) Designated Contracting States :
AT BE CH DE DK ES FR GB GR IT LI LU NL SE

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(54) Medical device for localizing a lesion.

(57) A medical device (10) for localizing a non-palpable breast lesion (20). The device includes a tubular introducer needle (11) and a wire guide (14) positioned therein for inserting into a breast (25) to the site of the lesion. The wire guide includes a distal portion (16) which is preformed into a resilient helical coil configuration for locking into position about the lesion. The distal portion includes a superelastic metallic alloy for maintaining the helical coil configuration after repeated extensions from and retractions into the needle passageway. With a visualization aid such as an X-ray film or ultrasound, a radiologist typically inserts the needle with the wire guide positioned therein into the breast to the site of the lesion and extends the distal portion of the wire guide from the needle. The distal end of the needle includes a plurality of indentations for enhancing the ultrasound visualization thereof. As the distal portion of the wire guide emerges from the needle, the acuate distal end (17) of the wire guide cuts into and scribes a helical path about the tissue distal to the lesion. The remainder of the distal portion of the wire guide follows the path scribed by the acuate distal tip and locks about the tissue distal to the lesion. Should the needle and wire guide not be appropriately positioned, the distal portion of the wire guide is retracted into the passageway of the needle to reposition the ne dle and guide. After desired positioning, the ne dle is removed with the wire guide remaining in a locked position distally about the lesion for guiding guides the surgeon to the lesion site during subsequent surgery.

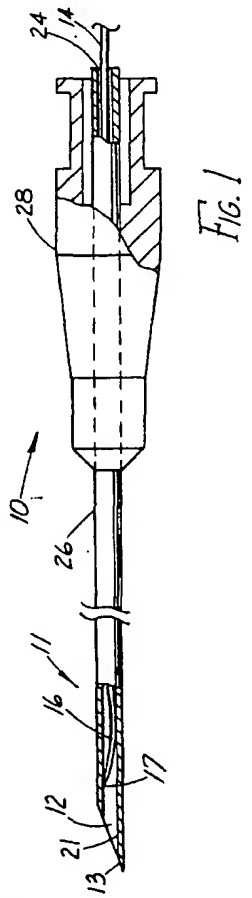

FIG. 1

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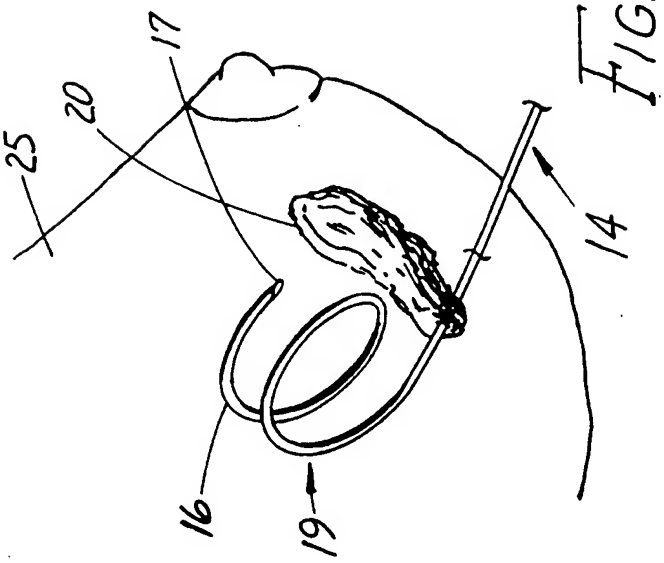

FIG. 7

This invention relates to medical devices for localizing lesions.

Localization needles or wire guides are utilized for preoperative marking of nonpalpable breast lesions. Typically, a needle cannula having a wire guide contained therein is inserted into the female breast and preferably positioned within two centimeters of the lesion. A mammogram or other visualization aid is used to confirm the position of the distal needle end. If the needle is not accurately positioned with respect to the lesion, the needle is repositioned, and another mammogram is taken to visualize the repositioning of the needle end with respect to the lesion. When the needle position is acceptable, the wire guide is extended from the distal end to localize the breast lesion for recision by a surgeon. Alternatively, the wire guide is maintained in a fixed position while the needle is removed to expose the wire guide contained therein. Similarly, the distal end of the wire guide localizes the breast lesion for recision by the surgeon. A number of prior art wire guides are utilized for localizing breast lesions. One in particular is the Kopans breast lesion localization needle that includes a spring-hook wire guide that is manufactured by Cook, Inc. of Bloomington, Indiana.

A number of repositionable localization systems are also presently available, such as the HAWKINS (Registered Trade Mark) breast lesion localization system manufactured by Boston Scientific Corporation of Watertown, Massachusetts.

Another repositionable localization system is the Homer MAMMALOCK (Registered Trade mark) needle/wire localizer, with a J-hook wire, which is available from Namic (Registered Name) of Glens Falls, New York. The J-hook wire tip protects the breast tissue from needle point penetration during breast compression.

Another repositionable wire guide with a J-hook configuration is disclosed in U.S. Patent No. 4,616,656. This repositionable wire guide is subject to the same disadvantages as those of the MAMMALOCK J-hook wire guide. Furthermore, the J-hook wire guide does not fixedly position or lock in breast tissue and is easily dislodged during transportation or movement of the patient. In addition, the J-hook wire tip design is hard for the surgeon to palpate.

According to the present invention, there is provided a device as defined in claim 1, or a wire-guide as defined in claim 2.

The helical coil configuration with a lateral orientation provides a significant advantage over prior art J-hook tip designs as well as that of a corkscrew having a passageway with a longitudinal orientation.

The distal end of the guide is shaped to facilitate penetration and also shaped to guide the penetration in a particular manner, i.e. in the spiral or helical format. With an inner wedge shaped cutting dge, and an outer chamfer d dge, the guide end is guided inwardly.

Brief description of th drawings

FIG.1 depicts an mbodim nt of the present invention;

FIG.2 depicts a wire guide of FIG.1;

FIG.3 depicts a cross-sectional view of the distal portion of the wire guide of FIG.2;

FIG.4 depicts the wire guide of FIG.1 positioned within a back loading cannula;

FIG.5 depicts the transfer of the wire guide from the back loading cannula of FIG.4 into the tubular introducer needle of FIG.1; and

FIGs.6 and 7 depict the insertion of the medical device of FIG.1 into a breast for localizing a nonpalpable breast lesion.

Depicted in FIG.1 is an illustrative embodiment of medical device 10 comprising a tubular introducer needle 11 and a wire guide 14 positioned in passageway 12 of the needle for insertion into a breast to the site of a nonpalpable lesion. With a visualization aid such as an X-ray film or ultrasound, a radiologist typically inserts the needle with the wire guide positioned therein into the breast to the site of the lesion. When inserted, the radiologist extends distal portion 16 of the wire guide from tapered distal end 13 of the needle, which assumes a preformed resilient configuration of substantially at least one or almost one complete coil and preferably a helical coil distally about the breast lesion. Another X-ray or ultrasound is taken to confirm the positioning of the needle and the wire guide distally about the breast lesion. Should the needle and wire guide not be appropriately positioned, the distal portion of the wire guide is retracted into the passageway of the needle. The needle and wire guide are then repositioned within the breast closer to the lesion, and another X-ray or ultrasound is taken to confirm the repositioning of the needle and extended distal portion of the wire guide. After the needle and wire guide are properly positioned, the needle is removed from the breast with the wire guide and the distal portion thereof in the helical coil configuration, thereby locking the guide in a position distal to the lesion to guide the surgeon to resect the lesion within a wedge of breast tissue surrounding the wire guide.

Needle 11 comprises cannula 26 having passageway 12 extending longitudinally therethrough between proximal end 24 and tapered distal end 13 for positioning the wire guide therein. Cannula 26 is a 20-gauge thin-wall, plug-drawn stainless steel tube, which is commercially available from K-Tube Corporation, San Diego, California. The plug-drawn stainless steel tube provides cannula 26 with a smooth, seamless interior surface 21 which prevents the pointed distal end 17 of th wire guide from catching and lodging on th interior surface of the ne dl . N edle

11 is approximately 11.5cms in length and is silicone coated for easy insertion into the breast. Cannula 26 includes distal end 13 tapered in a well-known venous bevel and proximal end 24 with a well-known female Luer-lock connector hub 28 insert moulded thereabout for ease of handling and for connection to a syringe for injection and irrigation of fluids.

Depicted in FIG.2 is wire guide 14 with straight portion 15 and distal portion 16 preformed into a resilient helical coil configuration 19 which is preferably conical. The wire guide, or only the distal portion 16, is comprised of a pre-formed metal or a superelastic metallic alloy such as nitinol which is commercially available from, for example, Nitinol, Saratoga, California or U.S. Shape Memory Applications, Inc., Sunnyvale, California. This superelastic metallic alloy in the preferred embodiment is nickel and titanium based and has a predetermined transformation temperature below that of the normal operating environment of the wire guide. In particular, the transformation temperature of wire guide 14 is in the range of 0-10 degrees Celsius, which is well below the body temperature of patients into whom the wire guide is to be inserted. When positioned in the passageway of a cannula such as that of needle 11, preformed distal portion 16 assumes an unwound configuration as depicted in FIG.1.

By way of example, wire guide 14 comprises approximately 20.5cms of 0.033cms (0.013") diameter nitinol wire sized for insertion through passageway 12 of tubular introducer needle 11. As depicted in FIG.2, wire guide 14 includes proximal portion 27 and distal portion 16, which is preformed into a resilient conical helical coil configuration 19 having acuate distal end 17 for cutting into and locking distally about the nonpalpable breast lesion. The helical coil configuration can extend to substantially one 180 degree turn to assume a minimum locking position, but preferably includes up to approximately two complete turns as shown. A cylindrical helical coil of conical configuration is also contemplated. The resilient helical coil configuration 19 follows a path scribed by acuate distal tip 17 as distal portion 16 is extended from passageway 12 of the needle to localize the nonpalpable breast lesion. Passageway 18 extending longitudinally through the helical coil configuration is laterally oriented with respect to straight portion 15. The lateral orientation locks the distal portion in place and prevents removal from or further insertion about the breast lesion when the straight portion is either pulled or pushed.

Depicted in FIG.3 is a cross-sectional view of distal portion 16 having acuate distal end 17 taken along the line 3-3 of FIG.2. This cross-sectional view of the distal portion illustrates the conical helical coil configuration 19 of the wire guide with longitudinal passageway 18 xtending therethrough.

Depicted in FIG.4 is back loading cannula 22 for positioning wire guide 14 therein and loading the wire guide into needle 11 after the needle has been positioned into, for example, the breast. Back loading cannula 22 is another piece of 20-gauge, thin-wall stainless steel tube similar to that of needl 11. As shown, straight portion 15 of the wire guide is inserted into the passageway 30 of the cannula through distal end 29 and out proximal end 23. The back loading cannula is brought into position with the conical helical coil configuration of distal portion 16 of the wire guide. The straight portion of the wire guide is pulled to retract the distal portion of the wire guide into the passageway of the back loading cannula. When fully retracted, the distal portion of the wire guide assumes an unwound configuration for positioning within the passageway of the needle.

To position the wire guide within the passageway of a positioned needle, distal end 29 of the back loading cannula is abutted against the proximal end 24 of the needle with male Luer-lock connector cap 31 as shown in FIG.5. The cap includes a passageway therein for aligning the two passageways of the cannulas. When the two pieces of cannula are abutted together, the distal portion of wire guide 14 is extended from distal end 29 of passageway 30 and repositioned into passageway 12 of the needle while maintaining an unwound configuration. The distal end of the needle cannula is sandblasted or, preferably, includes a plurality of semispherical indentations 32 formed in the outer surface thereof to enhance the ultrasound imaging of the distal needle end. Such ultrasound-enhanced needles are commercially available from Cook Urological Incorporated, Spencer, Indiana.

Depicted in FIGs.6 and 7 is medical device 10 comprising tubular introducer needle 11 containing wire guide 14 which is inserted into a breast 25 for localizing nonpalpable breast lesion 20. Wire guide 14 is extended from distal end 13 of needle 11. As the wire guide emerges from the needle, acuate distal end 17 cuts into and scribes a conical helical path distally about the tissue surrounding the breast lesion. The remainder of distal portion 16 follows the helical path scribed by acuate distal end 17. In this manner, distal portion 16 resumes a preformed helical coil configuration 19 which includes longitudinal passageway 18 therethrough for holding and locking the distal portion of the wire guide distally about lesion 20. The resilient helical coil configuration resists being dislodged from its distal position about the lesion during subsequent movement of the patient.

It is to be understood that the above-described medical device including a wire guide having a preformed helical coil configuration is merely an illustrative embodiment of the principles of this invention and that other wire guides and configurations thereof for locking the guide distally about a breast lesion may be devised by thos skill d in the art. In particular, the distal portion of th wire guid may be preformed into

any resilient configuration which is assumed when extended from the distal end of an introducer needle. It is contemplated that other superelastic alloys may be utilized with the distal portion of the guide for assuming the preformed locking configuration as well as being able to retract into the introducer needle for repositioning about the lesion. A conical or cylindrical helical coil configuration having a passageway extending longitudinally from the straight portion of the guide is also contemplated.

Claims

1. A medical device for localizing a nonpalpable lesion in a breast, comprising: a tubular needle (11) having a passageway (12) extending therethrough for accommodating a retractable wire guide, said needle comprising a distal end (13) tapered for insertion into the site of said lesion; said wire guide having a straight portion (14) and a metallic preformed distal portion (16), characterised in that the distal portion is preformed into a resilient configuration, of substantially at least more than a 180 degree turn.

2. A wire guide for localizing a nonpalpable lesion in a breast, said guide comprising: a straight portion; and a distal portion preformed into a resilient configuration of substantially more than a 180 degree turn, said guide being for use in the device of claim 1, and being of material and configuration such that it can be smoothly inserted into and smoothly withdrawn from the region of the lesion.

3. The device of claim 1 or guide of claim 2, characterised in that the resilient configuration is in the form of at least one coil, with an acuate distal end (17).

4. The device or guide of claim 3, characterised in that said resilient configuration is in the form of a helical configuration.

5. The device or the guide of claim 4, characterised in that said distal portion resilient configuration assumes an unwound configuration when positioned in said passageway of said needle, said distal portion resuming the resilient helical coil configuration as said distal portion of said wire guide is extended from said passageway of said needle, said helical configuration including a passageway (18) extending longitudinally through and laterally from said straight portion.

6. The device of claim 1,3,4 or 5, or the guide of claim 2,3,4 or 5, characterised in that said distal end of the wire guide is of super lastic metallic alloy.

7. The device or guid of claim 6, characterised in that the alloy is of nickel and titanium, and/or of material having a predetermined transformation temperature which is normally below the normal operating temperature.

8. The device of any one preceding device claim, further characterised by a second cannula (22) having a distal end (29) and a passageway (30) extending longitudinally therethrough; wherein said distal portion includes an unwound configuration for positioning in said passageway of said second cannula; and wherein the first mentioned cannula includes a proximal end, said distal end of said second cannula piece abutting against said proximal end of said first cannula when transferring said distal portion of said wire guide in said unwound configuration from said passageway of said second cannula to said passageway of said first cannula piece.

9. The device of claim 8, further characterised by a cap (31) having a passageway extending longitudinally therein sized for reviewing said first and second cannulas and aligning said passageways thereof, the first cannula optionally having a plurality of indentations in an outer surface thereof about said distal tapered end, for guidance purposes.

10. A medical device for localizing a nonpalpable lesion in a breast comprising: a tubular introducer needle including a first cannula having a first distal end tapered for insertion into said breast to the site of said lesion, a first proximal end, a first passageway extending longitudinally between said first ends, a plug-drawn interior surface about said first passageways, and an outer surface having a plurality of semispherical indentations therein about said first distal end; a second cannula including a second distal end, a second proximal end, a second passageway extending longitudinally between said second ends and a second plug-drawn interior surface about said second passageway; a connector having a passageway extending longitudinally therein and sized for receiving said first and second cannulas and aligning said passageways thereof; and a wire guide having a straight portion and a distal portion, said distal portion including a superelastic, nickel and titanium metallic alloy and being preformed into a resilient helical coil configuration including at least more than a 180 degree turn, an acuate distal end, and a passageway xt nding longitudinally therethrough and laterally from said straight portion, said alloy having a predeter-

mined transformation temperature, said distal end portion assuming an unwound configuration when positioned in said first passageway of at least one of said first and second cannulas, said at least more than a 180 degr e turn following a path scribed by said acuate distal end as said distal portion is extended from said first passageway at said tapered first distal end of said cannula, said second distal end of said second cannula abutting against said first proximal end of said first cannula when transferring said distal portion of said wire guide in said unwound configuration from said second passageway of said second cannula to said first passageway of said first cannula.

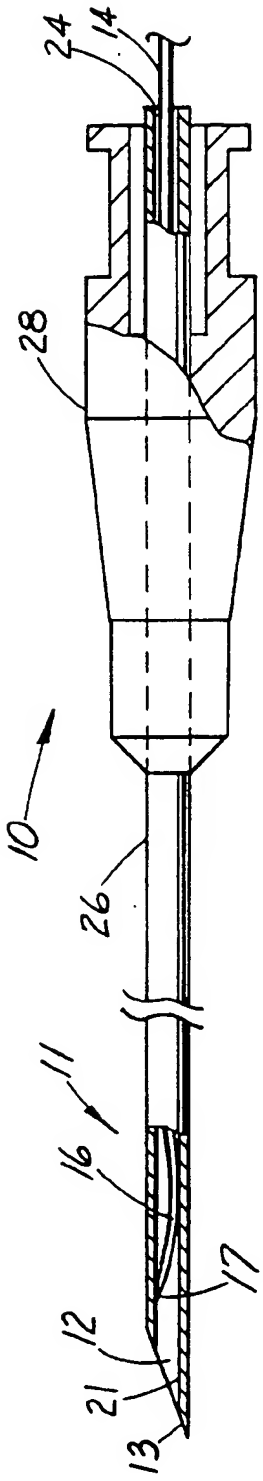

FIG. 1

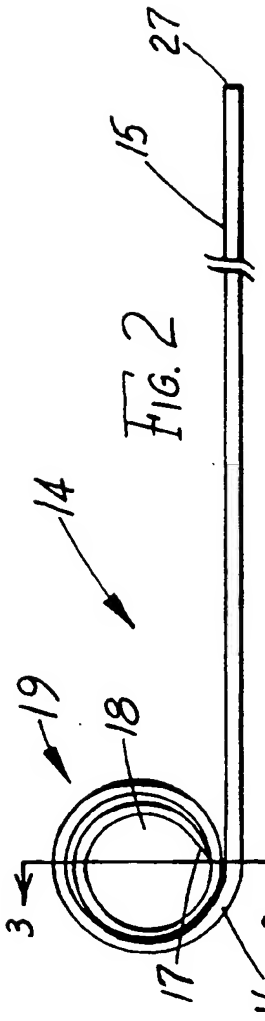

FIG. 2

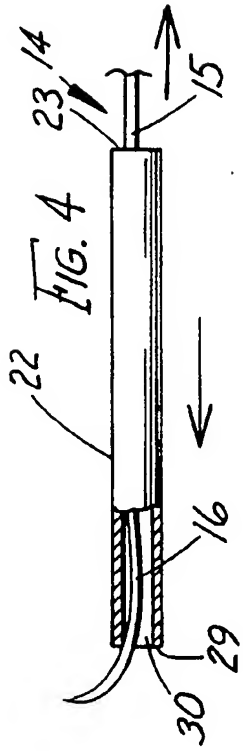

FIG. 4

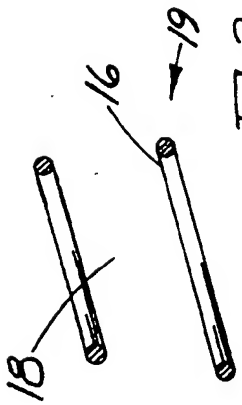

FIG. 3

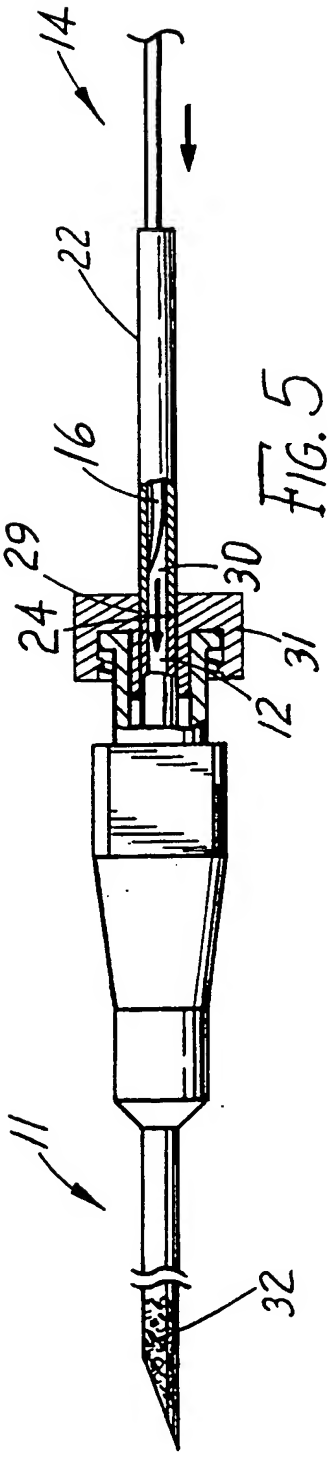

FIG. 5

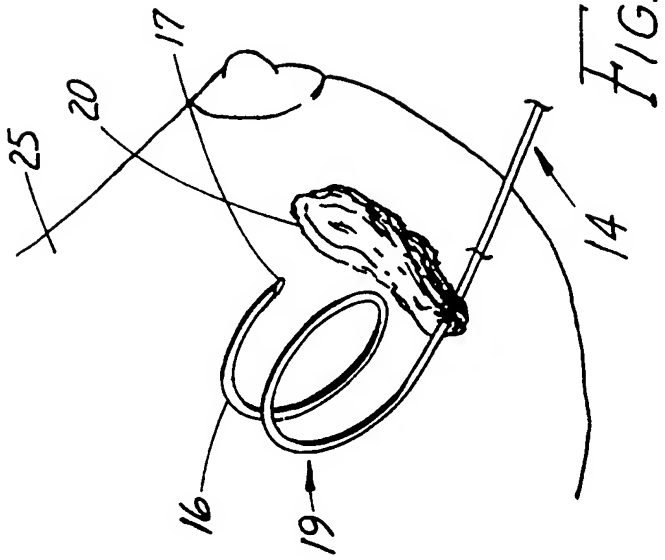

FIG. 7

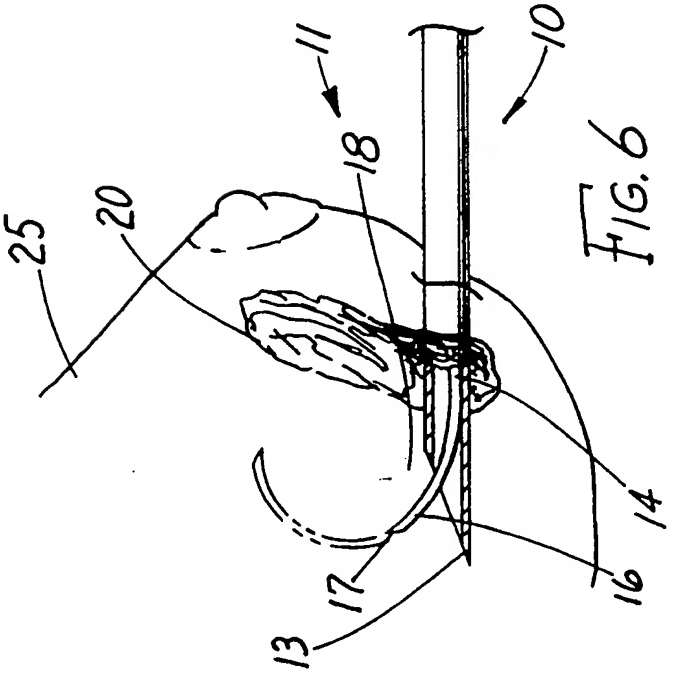

FIG. 6

European Patent Office

EUROPEAN SEARCH REPORT

Application Number

EP 91 30 9336

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int. Cl.5)
A,D	WO-A-8 605 378 (NICHOLSON) * claim 5; figures 1-3 *	1,2,10	A61B19/00 A61B17/34
A	EP-A-0 129 634 (ORETTNER) * page 4, line 6 - line 22; figures 1-3 *	1,2,10	
A	BE-A-707 070 (BREARD) * page 3, line 11 - page 4, line 15; figures 1-3 *	1,2,10	
A	DE-A-1 566 139 (PORTHEINE) * page 3, line 1 - line 33; figures 1,2 *	1,2,10	
			TECHNICAL FIELDS SEARCHED (Int. Cl.5)
			A61B A61M

The present search report has been drawn up for all claims

Place of search	Date of completion of the search	Examiner
THE HAGUE	24 JANUARY 1992	MOERS R.

CATEGORY OF CITED DOCUMENTS

X : particularly relevant if taken alone
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